K083478

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 17 2009

As required by section 807.92(c)

5 -1 GENERAL INFORMATION

Trade Name	SMOOTHLIPO™ SYSTEM
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	GEX
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	K073617: PHARAON LIPO by OSYRIS INC.
Submitter	Elemé Medical, Inc. Heron Cove Office Part 10 Al Paul Lane, Suite 102 Merrimack, NH 03054
Contacts	Michail M. Pankratov, Vice President, Clinical & Regulatory Affairs mpankratov@elememedical.com Phone: 1-603-816-1645 Fax: 1-603-662-4762

5 -2. DEVICE DESCRIPTION

The SMOOTHLIPO is the medical laser device using a diode laser module with emission of a beam of coherent light at 970nm ± 10 nm at a maximum power of 25W. The laser module consists of laser diodes assembled in series and optically aligned in order to focus in an optical fiber with the core of 600µm. The optical fiber is connected to the laser module via a SMA 905 connector. The SMOOTHLIPO laser includes power supply for the laser (50A, 2V) and a Peltier element built on a ventilated radiator for efficient functioning of the device.

In addition, functional electronics is provided to allow for laser parameter setting and the safe functioning of the device. The adjustments of parameters is achieved through a TFT (touch) screen and a tactile flagstone.

5 - 3. INTENDED USE

SMOOTHLIPO is intended for laser-assisted lipolysis

5 - 4. PERFORMANCE DATA

SMOOTHLIPO conforms to Guidance on the content and organization of a premarket notification for a medical laser (June 1995) and to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).

SMOOTHLIPO conforms to 21CFR part 1040.10 and 1040.11.

5 - 5. SUBSTANTIAL EQUIVALENCE

SMOOTHLIPO has the same intended use, material design and function as predicate device PHARAON LIPO (K073617).

In essence, the SMOOTHLIPO which is manufactured by Osyris is identical to PHARAON LIPO 980 laser from Osyris in its manufacturing, performance, and indications.

Summary preparation date: 11/20/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2009

Elemé Medical, Inc.
% Michail M. Pankratov, MD, PhD
VP, Clinical and Regulatory Affairs
Heron Cove Office Park
10 Al Paul Lane, Suite 102
Merrimack, New Hampshire 03054

Re: K083478
Trade/Device Name: SMOOTHLIP™ System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 5, 2009
Received: March 6, 2009

Dear Dr. Pankratov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

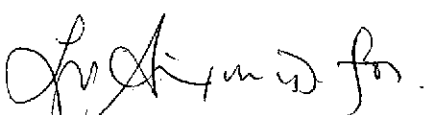
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): [redacted]

Device Name: **SMOOTHLIPO™ System**

Indications for Use: The SMOOTHLIPO is intended for laser-assisted lipolysis

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083478